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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,447	04/06/2001	Oswaldo da Costa e Silva	16313-0037	6900

29052 7590 04/30/2003

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04/30/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,447

Applicant(s)

E SILVA ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The Amendment filed January 22, 2003, paper no.13, has been entered.

Claims 1-35 are cancelled.

Claims 36-58 are newly added.

Claims 36-58 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 36 and 53, and claims 42-46 dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth for claims 1-2, 6-11, 15 and 18-20 in the office action mailed October 21, 2002.

Applicants' arguments filed January 22, 2003, have been fully considered but they are not persuasive.

Applicants argue that the rejection is mooted by the cancellation of claims 1-2, 6-11, 15 and 18-20 (reply page 7).

The Office maintains that the rejection is not mooted by the cancellation of claims 1-2, 6-11, 15 and 18-20, because the newly submitted claims do not recite any features that indicate the specific structural identity of the required coding nucleic acid. Claims 36 and 53 are drawn to

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methods and plant cells that require a *Physcomitrella patens* Signal Transduction Stress-Related Protein coding nucleic acid whose expression in the plant cell results in increased tolerance to drought and/or low temperature. While the rejected claims do recite that the coding nucleic acid is a *Physcomitrella patens* Signal Transduction protein, this limitation does not sufficiently distinguish the coding nucleic acid from other nucleic acids from *Physcomitrella patens* or from other organisms that encode Signal Transduction proteins, as an enormous number of structurally and functionally diverse sequences are known to encode Signal Transduction proteins.

Claims 36-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plant transformed with a nucleic acid of SEQ ID NO:7 encoding a polypeptide of SEQ ID NO:12, said plant exhibiting increased tolerance to drought and freezing stress, and while being enabling for a transgenic plant transformed with a nucleic acid that specifically hybridizes to the complement of SEQ ID NO:7, said plant exhibiting increased tolerance to drought and freezing stress, does not reasonably provide enablement for a transgenic plant transformed with a nucleic acid of SEQ ID NO:7 encoding a polypeptide of SEQ ID NO:12, said plant exhibiting increased tolerance to drought or low temperature, or a transgenic plant transformed with a nucleic acid that specifically hybridizes to the complement of SEQ ID NO:7, said plant exhibiting increased tolerance to drought or low temperature, or for transgenic plants transformed with a *Physcomitrella patens* Signal Transduction Stress-Related Protein coding nucleic acid, or for transgenic plants transformed with a polynucleotide encoding a polypeptide having at least 80% sequence identity with SEQ ID NO:12, for the reasons of record set forth for claims 1-11 and 15-23 in the office action mailed October 21, 2002, and for the reasons set forth below.

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Applicants' arguments filed January 22, 2003, have been fully considered but they are not persuasive.

Applicants argue that the present disclosure of the expression of five STSRP coding nucleic acids in a plant sufficiently describes an appropriate level at which to express other STSRP coding nucleic acids such that the plant's tolerance to environmental stress is increased (reply pages 7-8).

First, while the specification does disclose five DNA molecules isolated from *Physcomitrella patens* that encode different types of proteins homologous to known signal transduction proteins, three of which improve drought stress tolerance and freezing stress tolerance when expressed in transgenic *Arabidopsis* plants, and two of which improve drought stress tolerance when expressed in transgenic *Arabidopsis* plants, the five DNA molecules encode proteins that exhibit homology to structurally and functionally distinct groups of signal transduction proteins. The disclosure of five DNA molecules isolated from *Physcomitrella patens* that encode proteins exhibiting homology to structurally and functionally distinct groups of signal transduction proteins does not provide sufficient guidance for one skilled in the art to discriminate between signal transduction protein coding sequences whose expression would increase a plant's tolerance to environmental stress and signal transduction protein coding sequences whose expression would not increase a plant's tolerance to environmental stress, because an enormous number of structurally and functionally diverse sequences are known to encode signal transduction proteins, both within a particular organism and between groups of organisms.

Second, while the specification discloses that expression of a nucleic acid of SEQ ID NO:7 in transgenic *Arabidopsis* increases the plant's tolerance to both drought stress and freezing

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stress, the specification does not provide any guidance with respect to how to express SEQ ID NO:7 in a transgenic plant such that the plant's tolerance to drought stress alone is increased, or such that the plant's tolerance to freezing stress alone is increased.

Third, the specification does not provide sufficient guidance for one skilled in the art to discriminate between polynucleotides encoding a polypeptide having at least 80% sequence identity with SEQ ID NO:12 whose expression would increase a plant's tolerance to environmental stress and polynucleotides encoding a polypeptide having at least 80% sequence identity with SEQ ID NO:12 whose expression would not increase a plant's tolerance to environmental stress. Polypeptides having at least 80% sequence identity with SEQ ID NO:12 include a large number of protein variants in which one or more of the 628 amino acids of SEQ ID NO:12 will vary, yet the specification provides no guidance with respect which amino acids may vary, and in what way they may vary, such that one skilled in the art could identify, without undue experimentation, a polypeptide having at least 80% sequence identity with SEQ ID NO:12 whose expression would increase a plant's tolerance to environmental stress.

Fourth, no function is recited for the nucleic acids of claims 39-41 or 47-51.

Claims 36-39, 41, 46-56 and 58, and claims 40, 42-45 and 57 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite are indefinite in the recitation of "Stress-Related Protein" or "STSRP", for the reasons of record set forth for claims 1-5, 15-17 and 19-23 in the office action mailed October 21, 2002, and for the reasons set forth below.

Applicants' arguments filed January 22, 2003, have been fully considered but they are not persuasive.

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Applicants argue that they are acting as their own lexicographer, and that the terms are defined in the specification (reply page 8).

The Office maintains that the recitation of "Stress-Related Protein" or "STSRP" in the claims is unclear because the relationship between stress and the protein is not discernable. The Office further maintains term definitions set forth in the specification do not limit the terms "Stress-Related Protein" and "STSRP" set forth in the claims.

Claims 36, 46, 52, 53, 56 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "low" temperature, as "low" is a relative term that lacks a comparative basis.

Claims 37 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "PLC-2". The meaning of "PLC-2" is unclear, as an acronym may have more than one meaning.

Claims 39, 49 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "hybridizes under stringent conditions", for the reasons of record set forth for claims 5, 17 and 23 in the office action mailed October 21, 2002, and for the reasons set forth below.

Applicants' arguments filed January 22, 2003, have been fully considered but they are not persuasive.

Applicants argue that the rejection does not apply to the newly submitted claims as they recite specific hybridization conditions (reply page 9).

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The newly submitted claims are indefinite because they do not recite the specific conditions under which the coding nucleic acid hybridizes. The claims state that the GBSRP coding nucleic acid “hybridizes under stringent conditions to a sequence”, but then they recite only that the stringent conditions comprise “at least one wash” in a 0.2X SSC, 0.1% SDS solution at 50°C. In other words, the rejected claims do not recite the specific conditions under which the coding nucleic acid hybridizes, rather the rejected claims recite the specific conditions under which the coding nucleic acid is washed after hybridization.

Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "a forage crop", for the reasons of record set forth for claim 9 in the office action mailed October 21, 2002, and for the reasons set forth below.

Applicants' arguments filed January 22, 2003, have been fully considered but they are not persuasive.

Applicants argue that what is encompassed by “forage crop” would be well known by one of skill in the art (reply page 9).

The Office maintains that the argument that what is encompassed by “forage crop” would be well known by one of skill in the art is not relevant to the instant rejection, as the claim is to a plant, and a forage crop is not a plant.

Claims 53, 56 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claims 53, 56 and 59 are missing the essential step of expressing a Signal Transduction Stress-Related Protein. In the absence of expression of a Signal Transduction

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Stress-Related Protein, the methods of claims will not result in the production of a transgenic plant with an increased tolerance to environmental stress as set forth in the preamble.

Claim Rejections - 35 USC § 102

Claims 36, 43, 45-46 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Fan et al. (The Plant Cell, Vol. 9, 2183-2196, December 1997), for the reasons of record set forth for claims 1, 5, 8, 10, 17-19 and 23 in the office action mailed October 21, 2002.

Applicants' arguments filed January 22, 2003, have been fully considered but they are not persuasive.

Applicants argue that Fan et al. teach away from the instant invention by teaching suppression of gene expression through the use of an antisense molecule increases plant stress resistance, whereas Applicants teach that expression of certain genes results in increased plant stress resistance. Applicants also argue that the PLD α gene would not be encompassed by the claims as a Pairwise BLAST comparison indicates that PLD α and PLC-2 exhibit no significant homology, such that a PLD α coding nucleic acid would not be expected to hybridize to SEQ ID NO:7 under stringent conditions (reply page 11).

With respect to the argument that that Fan et al. teach away from the instant invention by teaching suppression of gene expression through the use of an antisense molecule while Applicants teach that expression of certain genes results in increased plant stress resistance, the Office notes that the rejected claims do not specify that the Signal Transduction Stress-Related Protein coding nucleic acid needs to be in a sense orientation when expressed, or that expression of the Signal Transduction Stress-Related Protein coding nucleic acid results in the production of

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a Signal Transduction Stress-Related Protein. The rejected claims require only "expression".

With respect to the argument that PLD α and PLC-2 exhibit no significant homology, the Office notes that the currently rejected claims do not require homology or hybridization. Furthermore, while Fan et al. do not teach a coding nucleic acid obtained from *Physcomitrella patens*, the limitation "*Physcomitrella patens*" does not specifically limit the sequence used to transform the plants or cells, as discussed *supra* under 35 USC 112, first paragraph.

Claims 36, 43-46 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi et al. (The Plant Journal, 1995, Vol. 8, No. 3, 381-390), for the reasons of record set forth for claims 1-2, 5, 6, 8-10, 15, 17-20 and 23 in the office action mailed October 21, 2002.

Applicants' arguments filed January 22, 2003, have been fully considered but they are not persuasive.

Applicants argue that Shi et al. do not teach or suggest that expression of the soybean PI-PLC protein will increase a plant's environmental stress tolerance. Applicants also argue that the soybean PI-PLC amino acid sequence shows 44% identity with the PLC-2 polypeptide of SEQ ID NO:12, such that a PI-PLC coding nucleic acid would not be expected to hybridize to SEQ ID NO:7 under stringent conditions (reply pages 11-12).

With respect to the argument that Shi et al. do not teach or suggest that expression of the soybean PI-PLC protein will increase a plant's environmental stress tolerance, the Office maintains that the increased tolerance to environmental stress exhibited by the claimed plants and cells would be an inherent characteristic of plants and cells transformed with and expressing a Signal Transduction Stress-Related Protein coding nucleic acid. With respect to the argument that the soybean PI-PLC amino acid sequence shows 44% identity with the PLC-2 polypeptide of

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SEQ ID NO:12, such that a PI-PLC coding nucleic acid would not be expected to hybridize to SEQ ID NO:7 under stringent conditions, the Office notes that the currently rejected claims do not require any percent identity or hybridization. Furthermore, while Shi et al. do not teach a coding nucleic acid obtained from *Physcomitrella patens*, the limitation "*Physcomitrella patens*" does not specifically limit the sequence used to transform the plants or cells, as discussed *supra* under 35 USC 112, first paragraph.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

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Claims 37-41, 47-52 and 54-58 are deemed free of the prior art, due to the failure of the prior art to teach or suggest a nucleic acid sequence of SEQ ID NO:7 encoding a polypeptide of SEQ ID NO:12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
April 21, 2003

Phuong Bui
PHUONG T. BUI
PRIMA EXAMINER 4/21/03